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**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/386,850	08/31/99	ROSINSKI-CHUPIN	I 004900-169

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BURNS DOANE SWECKER & MATHIS L L P  
POST OFFICE BOX 1404  
ALEXANDRIA VA 22313-1404

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

7

DATE MAILED:

11/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.

09/386,850

Applicant(s)

R siniski-Chupin et al

Examiner

Karen Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 15-17 is/are pending in the applicat

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 15-17 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

### DETAILED ACTION

1. Please note that the examiner to which your application has been assigned at the PTO has changed.
2. Claim 1 has been canceled. Claims 15-17 have been added. Claims 15-17 are pending and examined on the merits.

### *Claim Rejections - 35 USC § 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 15, 16 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible specific utility or a well established utility.

The disclosed utilities for the SMR1 polypeptide (SEQ ID NO:1) or polynucleotides which encodes the SMR1 polypeptide, or polynucleotides which hybridize to the SMR1 polynucleotides, or antibodies generated to the SMR1 polypeptide are non-specified applications as a therapeutic reagent or uses in further experimental studies as a "laboratory reagent" as stated on pg 12, lines 35-36. The specification describes the SMR1 peptide as a maturation product of a polypeptide secreted by the submaxillary gland of the rat. The specification further discusses the induction of the SMR1 gene by androgens, and suggests that the SMR1 peptide may fulfil an important function specific for the male rat, and additionally suggests that SMR1 might be a precursor molecule controlling behavioral characteristics of the male rat. However, neither the specification nor any art of record teaches a "real world" utility for the SMR1 polypeptide, polynucleotide or anti-SMR1 antibodies nor is there taught a relationship to any specific diseases or establishment of SMR1 polynucleotide or polypeptide in the etiology of any specific diseases. The asserted utilities for SMR1 polypeptide, such as production of, antibodies apply to many unrelated polypeptide sequences. Therefore the production of antibodies to SMR1 is not

considered a "specific" utility, i.e., it is not specific to SMR1 polypeptide. Additional disclosed utilities for SMR1 are diagnosis of conditions and diseases characterized by expression of SMR1. The asserted utility of the SMR1 is based on the observation that androgens cause a higher accumulation of the mRNA of SMR1. However, there is no indication in the specification that a human homologue of SMR1 exists, and if it did exist, there is no evidence presented in the specification to correlate the over expression of any SMR1 human homologue with a disease state in the human. The claimed invention is not supported by a specific, substantial and credible asserted utility or a well-established utility. The specification essentially gives an invitation to experiment, wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acids.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not teach a relationship between rat SMR1 polypeptide and any specific diseases. The specification does not teach a human homologue to the SMR1 polypeptide, nor does it teach a molecular mechanism linking human SMR1 polypeptide to the etiology of any human diseases. As a result of the claimed invention not being supported by a substantial, specific and credible utility or a well-established utility for the reasons set forth in the rejection under 35 USC 101 above, one of skill in the art would be forced into undue experimentation in order to find a use for the claimed polynucleotides which encode SMR1 polypeptides.

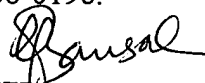
7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 15 and 16 recite "hybridize". Absent claim limitations directed to the stringency of the hybridization, the metes and bounds of the claims are unclear.

*Conclusion*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
**GEETHA P. BANSAL**  
**PRIMARY EXAMINER**

Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
November 17, 2000